ProMRI®
MR conditional device systems

ProMRI®

BIOTRONIK
excellence for life

Table of Contents

Basic Information **2**
About this Manual 2
Target Group 3
Intended Medical Use 4
An Overview of MR Conditional BIOTRONIK Products 5

Safety Warnings **9**
Magnetic Resonance Imaging - Possible Interactions 9
Contraindications 11
Preconditions and Basic Conditions for all Products 12
Conditions for Specific Products 14

MRI Examination **16**
Preliminary Examination 16
MRI Examination 19
Follow-up 20

Appendix A **21**
MR Conditional Symbol on the Label 21

Appendix B **22**
Combinations of Specific Products 22

1 Basic Information

About this Manual

Subject of this manual

The manual provides information about the safe application of an MR scan on patients with a BIOTRONIK device system, which consists of a pacemaker or ICD and the associated leads and has been labeled MR conditional.

This manual will focus particularly on the restrictive prerequisites and general conditions and safety measures that are to be adhered to before and during an MR scan using a BIOTRONIK device system.

What this manual doesn't include

Correct and safe use of the respective ICDs or pacemakers and leads is described in the technical manuals provided with the products and is not a subject of this manual.

Likewise, correct and safe use of an MRI scanner is not described in this manual unless directly related to an implanted BIOTRONIK device system.

Frequently used terms

An MR conditional device system allows patients who have such a system (consisting of an active device and one or more leads) to undergo an MR scan if certain requirements and conditions are fulfilled.

Such products are labeled with the MR conditional symbol on their packaging.

ProMRI is the BIOTRONIK name and trademark for these products.

Affected products

The procedures for the preparation and conduction of an MR scan described in this manual relate only to implantable leads, pacemakers, and ICDs that are declared MR conditional by BIOTRONIK.

The behavior of a certain combination of one or more leads and an active device is tested under MR scan conditions for this purpose. Thereby, specific criteria and conditions, which are each precisely defined, may apply for different device systems.

Target Group

Cooperation between professionals from two areas of expertise

This manual is intended for physicians and medical staff who have the knowledge and experience required to prepare and perform MRI scans on patients with an ICD or pacemaker.

Preparation and conduction of an MR scan on an ICD or pacemaker patient require close cooperation between a cardiology professional, as a specialist for the device system, and a radiology professional, as a specialist for the MR scan.

The following sections describe the tasks that each of these specialists are responsible for.

Knowledge required by the cardiology specialist

A cardiology professional is required to select and/or approve the patient for the MR scan. Additionally, they must test the device system before the exam, put the device in a special MRI mode, ensure its functionality after the exam and program it back to the mode which was active before the MR scan.

The expert knowledge required by the cardiology professional includes the following areas and subjects:

- Performing ICD or pacemaker therapy
- Handling of the BIOTRONIK programmer and especially the following activities:
  - Interrogating the active device
  - Performing follow-up
  - Switching parameters
- All associated risks, possible side effects, and the appropriate safety and therapy measures

Knowledge required by the radiology specialist

The radiology professional is responsible for the successful performance of the MR scan for the purposes of the desired diagnosis. Additionally, the radiology professional is also responsible for ensuring that the restrictive conditions, under which the exam is to be performed, are observed both before and during the MR scan.

The expert knowledge required by the radiology professional includes the following areas and subjects:

- Handling MRI scanners
- Preparation, performance and analysis of MR scans

Intended Medical Use

Active device and lead

The respective intended use of the pacemaker or ICD and lead(s) applies to the use of the device system.

Note: The technical manuals for the active device and the lead(s) are to be observed.

Patient selection, MRI indication

Before a patient with an MR conditional device system is selected for an MR scan, the following issues must be resolved:

- There must be a clear indication for the MR scan.

  This means that there is no doubt as to the predictable diagnostic benefit of the MR scan and that comparable results cannot be achieved with other less risky procedures.
- Risk/benefit analysis
- All of the exclusion criteria listed in this technical manual have been taken into consideration.
- The described restrictions and conditions for the MR scan are to be observed at all times.

Intended use

In the past, MR scans were always contraindicated for ICD or pacemaker patients.

If the relevant prerequisites and conditions are fulfilled, MR scans can now be conducted on patients with a combination of a BIOTRONIK active device and lead that has been tested for this purpose.

Residual risk

The expected risks and hazards are minimized by the measures listed in this manual. Nevertheless, a residual risk remains.

An Overview of MR Conditional BIOTRONIK Products

Devices and device systems

The behavior of a precisely defined device system, consisting of a pacemaker or ICD and at least one lead, has been tested under the conditions of an MR scan and labeled MR conditional.

However, due to the fact that both the active device and the lead are sold independently of each other, this manual informs the user about which combinations of an active device and a lead are MR conditional, and about the conditions and requirements that are to be observed for the respective combination.

MRI approval in the country

If you are planning to perform an MR scan with an MR conditional BIOTRONIK device system, please contact the responsible authorities or BIOTRONIK beforehand to determine whether these products are actually certified as MR conditional in your country or region.

MR conditional ICDs

The following ICDs are MR conditional:

Lumax models:

Model	**Order number:**
Lumax 740 VR-T	381 459
Lumax 740 VR-T DX	381 463
Lumax 740 DR-T	381 461
Lumax 740 HF-T	381 462
Lumax 640 VR-T	381 468
Lumax 640 VR-T DX	381 472
Lumax 640 DR-T	381 470
Lumax 640 HF-T	381 471

Iforia models:

Model	**Order number: DF-1 connection**	**Order number: DF4 connection**
Iforia 5 VR-T	390 119	390 121
Iforia 5 VR-T DX	390 123	
Iforia 5 DR-T	390 115	390 117
Iforia 5 HF-T	390 111	390 113
Iforia 7 VR-T	390 083	390 089
Iforia 7 VR-T DX	390 095	
Iforia 7 DR-T	390 069	390 075
Iforia 7 HF-T	390 056	390 062

Ilesto models:

Model	Order number: DF-1 connection	Order number: DF4 connection
Ilesto 5 VR-T	390 118	390 120
Ilesto 5 VR-T DX	390 122	
Ilesto 5 DR-T	390 114	390 116
Ilesto 5 HF-T	390 110	390 112
Ilesto 7 VR-T	390 082	390 088
Ilesto 7 VR-T DX	390 094	
Ilesto 7 DR-T	390 068	390 074
Ilesto 7 HF-T	390 055	390 061

MR conditional pacemakers

Note: For Evia, Entovis, Estella and Ecuro models up to incl. serial number 66237094 a maximum slew rate of 125 T/m/s per axis is valid.

The following pacemakers are MR conditional:

Evia models:

Model	Order number: uncoated	Order number: coated
Evia SR-T	371 998	372 034
Evia SR	371 997	372 033
Evia DR-T	371 996	372 032
Evia DR	371 995	372 031
Evia HF-T	381 534	381 535
Evia HF	381 532	381 533

Entovis models:

Model	Order number: uncoated	Order number: coated
Entovis DR-T	371 992	372 028
Entovis DR	371 991	372 027
Entovis SR-T	371 994	372 030
Entovis SR	371 993	372 029
Entovis HF-T	381 530	381 531
Entovis HF	381 528	381 529

Estella models:

Model	Order number: uncoated	Order number: coated
Estella DR-T	377 383	377 382
Estella DR	377 381	377 380
Estella SR-T	377 387	377 386
Estella SR	377 385	377 384

Ecuro models:

Model	Order number: uncoated	Order number: coated
Ecuro DR-T	377 367	377 366
Ecuro DR	377 365	377 364
Ecuro SR-T	377 371	377 370
Ecuro SR	377 369	377 368

MR conditional lead models

The following leads are MR conditional:

Pacemaker lead Safio S:

Lead model	Order number
Safio S 45	370 944
Safio S 53	370 945
Safio S 60	370 946

Pacemaker lead Solia S:

Lead model	Order number
Solia S 45	377 176
Solia S 53	377 177
Solia S 60	377 179

Pacemaker lead Solia T:

Lead model	Order number
Solia T 53	377 180
Solia T 60	377 181

ICD lead Linox smart ProMRI S:

Lead model	Order number
Linox^{smart} ProMRI S 65	377 166
Linox^{smart} ProMRI S 75	377 167

ICD lead Linox smart ProMRI SD:

Lead model	Order number
Linox^{smart} ProMRI SD 65/16	377 169
Linox^{smart} ProMRI SD 65/18	377 170
Linox^{smart} ProMRI SD 75/18	377 171

ICD lead Linox^{smart} ProMRI S DX:

Lead model	Order number
Linox^{smart} ProMRI S DX 65/15	377 211
Linox^{smart} ProMRI S DX 65/17	377 212

ICD lead Linox^{smart} ProMRI DF4 SD:

Lead model	Order number
Linox^{smart} ProMRI DF4 SD 65/16	394 102
Linox^{smart} ProMRI DF4 SD 65/18	394 103
Linox^{smart} ProMRI DF4 SD 75/18	394 104

Coronary sinus lead Corox ProMRI OTW:

Lead model	Order number
Corox ProMRI OTW 75 BP	381 487
Corox ProMRI OTW 85 BP	381 488
Corox ProMRI OTW-L 75 BP	381 492
Corox ProMRI OTW-L 85 BP	381 491
Corox ProMRI OTW-S 75 BP	381 489
Corox ProMRI OTW-S 85 BP	381 490

MR conditional device systems

Only very specific combinations of the above-mentioned active devices and leads are certified as MR conditional device systems.

Please see Appendix B for the combinations of ICDs or pacemakers and leads which can be used as a device system that is tested MR conditional.

2 Safety Warnings

Magnetic Resonance Imaging - Possible Interactions

Problematic interactions

Significant mechanisms which can lead to problematic interactions with device systems are described here.

Therefore, the conduction of MR scans for ICD or cardiac pacemaker patients is generally contraindicated.

MR conditional BIOTRONIK devices

BIOTRONIK has with its MR conditional systems developed devices on which the effects listed below on device systems and patients are minimized.

For this combination of lead and active device, conditions required for the responsible performance of MR scans have been tested and explained in this manual.

Fields in the MRI scanner

The following three types of fields are generated in an MR scan:

- **Static magnetic field**

  This is a consistently strong, homogenous magnetic field which is constantly present in the MRI scanner and its immediate surroundings, even if no scan is being performed.

- **Gradient magnetic fields**

  These are low-frequency pulsed magnetic fields with a relatively low amplitude.
  During the MR scan, the patient is exposed to three gradient magnetic fields that are perpendicular to each other.

- **HF field** (high frequency field)

  This is a high frequency electromagnetic field which activates the protons on their resonance frequency.
  It is switched on several times during the imaging process, but only for very short periods.
  The HF field is created by so-called emitting coils, which also serve as receiver coils.
  A differentiation is made between the emitting coils (body coils) integrated in the MRI scanner with the addition of optional local emitting coils (e.g. head coil with transmitting function).

Force of the static and gradient magnetic fields

Implanted ferromagnetic materials are subject to the force of these magnetic fields.

This means that implanted devices can subject the surrounding tissue to pressure, tensile force or vibrations.

The construction and choice of material in the MR conditional devices and compliance with the specified conditions serve to reduce these stresses to an acceptable minimum.

Interactions resulting from induced AC voltages

Gradient magnetic fields and electromagnetic high frequency fields can induce electrical AC voltages in metallic devices.

In some cases, these electrical energies can result in undesirable pacing or have a negative impact on the ICD or pacemaker.

Constructive measures on the MR conditional devices and the restrictive prerequisites for the arrangement and conduction of the MR scan reduce the probability of occurrence and the strength of this effect. However, this effect cannot be entirely excluded.

The accompanying emergency precautions are, among others, necessary in this case.

Thermal interactions

High-frequency electromagnetic fields induce electric voltages in the lead which cause current conduction through the lead and the tissue electrically connected to the lead.

This flow of current in turn causes warming at the electrical points of contact between the lead and the tissue which can result in thermal damage to the surrounding tissue.

This thermal tissue damage can be temporary or lasting and can cause deterioration of the lead's pacing and sensing functions.

Gradient magnetic fields can cause warming of the device housing which can lead to thermal exposure and damage to the surrounding tissue.

Due to the constructive composition of the MR conditional devices, and the compliance with the tested conditions and restrictions for the MR scan, these thermal effects are kept to a tolerable measure.

Image interference and artifacts

Not only can the MR scan have undesirable effects on the patient or the device system, but the implanted devices can also have a negative impact on the MR scan.

If the devices are outside the scanning area, they can cause slight image distortion and interference.

If a device is within the area shown by the MRI scanner, then artifacts, distortion and interference are probable. Consider this when selecting the image calculation parameters and the depicted area.

Note: Permissible positioning zone
A permissible positioning zone for each MR conditional device system is specified in the relevant part of this manual.
The limits of the permissible positioning zones regulate the size and location of the scan exclusion zone.

Contraindications

Preliminary notes

The indications and contraindications for implantation of certain leads and ICDs or pacemakers and the application of the respective cardiological therapies are not included in this manual. Please refer to the technical manuals of the respective devices for this information.

This manual only deals with aspects that are relevant within the MR scan context.

The manual does not deal with the contraindications of MRI applications, which do not result from interactions with a device system.

Contraindications

- An MR scan on a device system patient is always contraindicated for device systems which have not been identified as MR conditional by BIOTRONIK and have not been certified for MRI applications by a responsible authority.
- An MR scan on a patient with an MR conditional device system is also contraindicated when any of the conditions listed under Preconditions and Basic Conditions for all Products, p. 12 is not adhered to.
- An MR scan on a patient with an MR conditional device system is also contraindicated when one of the specific conditions that applies to a particular device system is not adhered to.

Preconditions and Basic Conditions for all Products

Basic principles

Safe conduction of an MR scan on a patient having an implanted ICD or pacemaker is only possible under highly specific prerequisites and conditions.

MRI use is contraindicated in all other cases.

Preconditions for the patient and the device system

The following requirements must always be fulfilled to perform an MR scan with inclusion of a BIOTRONIK device system.

- The device system consists only of one or more leads and a pacemaker or ICD, which are each separately labeled MR conditional and can in combination constitute an MR conditional device system.

  See: An Overview of MR Conditional BIOTRONIK Products, p. 5
- There are no other devices in the patient's body.

  For example:
  — Other pacemakers or ICDs
  — Abandoned leads
  — Lead adapters
  — Lead extensions
- The patient does not have fever.
- The patient's height is at least 1.4 meters.
- The device system has been implanted for at least 6 weeks.
- The device system is in the patient's chest area.
- The ascertained pacing threshold does not lie above 2.0 V at 0.4 ms pulse width.
- The ascertained lead impedance is between 200 and 1500 ohms.
- The pacemaker or ICD is reprogrammed to a special MRI mode immediately before the MR scan.
- The conditions applicable to specific devices or device systems such as specific permissible positioning zones and minimum patient height are observed.

Requirements of the MRI scanner

The MRI scanner must meet the following conditions:

- Use of a clinical MRI system with a closed tube, cylindrical magnets and a static magnetic field strength of 1.5 T.
- The slew rate of the MRI scanner's gradient fields must not exceed 200 T/m/s per axis.

Note: For Evia, Entovis, Estella and Ecuro models up to incl. serial number 66237094 a maximum slew rate of 125 T/m/s per axis is valid.

- The HF field is generated solely by the body coil built into the MRI scanner.

  No additional local emitting coils are used.

Restrictions during the MR scan

The following conditions must be met during the MR scan:

- The MR scan must only be performed with the patient in dorsal position.
- The permissible positioning zone defined in the "Conditions for specific products" section must be observed.
- The overall accumulated time required during the MR scan for imaging as displayed by the MRI scanner must not exceed 30 minutes.
- The mean specific absorption rate for the whole body displayed by the MRI scanner must not exceed 2.0 W/kg.
- The head absorption rate displayed by the MRI scanner must not exceed 3.2 W/kg.
- Emergency equipment for resuscitation must be kept at hand and properly certified staff must be available.
- Monitor the patient's hemodynamics during the entire MR scan by continuously recording at least one of the following parameters:
  - — Blood oxygen saturation
  - — Blood pressure
  - — ECG

  Only use devices for this which are permitted for patient monitoring in an MRI environment.

Note: The ECG function integrated in the MRI scanner is often not permitted for patient monitoring.

- Any additional specific conditions only applicable to certain device systems must also be observed.

Conditions for Specific Products

General information

Several prerequisites and conditions for conducting an MR scan apply to more than one possible device combination, whereas other conditions are specifically defined for one particular condition.

This section describes the conditions that are specific to device systems.

MR conditional device systems

Please see Appendix B for the combinations of ICDs or pacemakers and leads which can be used as a device system that is tested MR conditional.

Specific conditions for device systems

In addition to the prerequisites and basic conditions for all products, special conditions apply to the combinations of pacemakers or ICDs and lead(s) listed in the Appendix:

- The total length of examination for the device system must be below 10 hours.

  Explanation of the term "total length of examination":
  When several MR scans are performed in a row on a patient with a device system, the length of each examination is recorded and these times are accumulated. This sum is almost equal to the total exposition time during which the devices were exposed to the strong magnetic field.

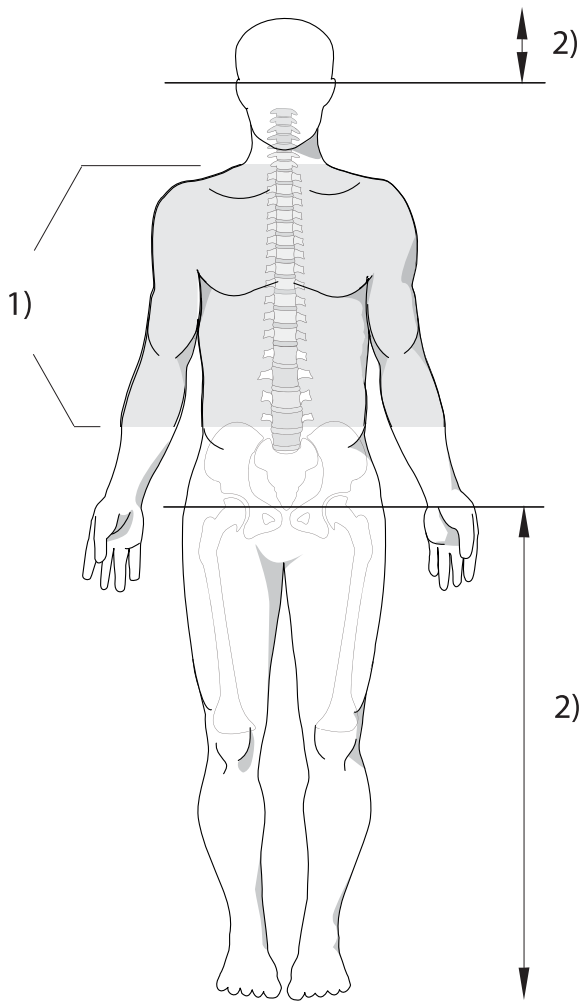
- Adherence to the permissible positioning ranges.

  The isocenter of the high-frequency coil should not be below eye level nor above the hip bone.
  In practice this means that the marker line of the laser light localizer, which is used for subsequent positioning of the patient within the MRI scanner, should not be set below eye level (lower edge of eye socket) and not above the hip bone (two fingers above the symphysis).
  These areas absolutely have to be adhered to during the MR scan.
  However, receiver only coils can also be positioned outside this area.
  As a result of this limitation and due to the technical specifications of the MRI scanner, no imaging data can be collected for this part of the body (the scan exclusion zone).

Permissible positioning zone and scan exclusion zone

The following applies to the device systems listed in the Appendix:

Sketch: permissible positioning zone and scan exclusion zone



Legend:

- 1) Scan exclusion zone
- 2) Permissible positioning zone

Starting from the foot end, the maximum allowed positioning mark for the isocenter is at the hip bone level or two fingers above the symphysis.
Starting from the top of the skull, the maximum allowed positioning mark for the isocenter is at the level of the eyes or the lower edge of the eye socket.
Imaging data can be obtained within the field of view of an MRI scanner and thus the scan exclusion zone depends on the MRI scanner's field of view.

3 MRI Examination

Preliminary Examination

Cooperation between specialists

Preparation and conduction of an MR scan on a patient with an ICD or pacemaker requires close cooperation between a specialist for the device system and a specialist for the MRI technology and MR scan.

One of these specialists must perform the steps described in the following for preparation of the MR scan, the patient and his or her device system.

The person responsible for each task depends on the activity or context of the scan.

Checking the suitability of the patient and the implanted system

Cardiology and radiology professionals are required for this step. Proceed as follows:

Step	Action
1	Check and ensure that all requirements pertaining to the patient and the device system described in the sections Preconditions and Basic Conditions for all Products, p. 12 and Conditions for Specific Products, p. 14 are met.
2	Make sure the technical and clinical basic conditions for the MR scan can be met and that the necessary preparations have been made.

Preliminary cardiological examination and MRI programming

Once the conditions for an MR scan have been clarified, preliminary examination and programming to an MRI mode by the cardiologist are the final and definitive preparation measures. Proceed as follows:

Step	Action
1	Apply the programming head of the programmer to the chest and interrogate the pacemaker or ICD.
2	Perform full follow-up and check the following preconditions for the MR scan: • Pacing threshold: max. 2.0 V / 0.4 ms • Lead impedance: 200 ... 1500 Ω • Battery charging status: min. 30%
3	Open the MRI program. There are two options: • Select **Follow-up → MRI**. • Select **Parameters → Program sets → Show MRI program**.
4	Read the preliminary and basic conditions in the `MRI checklist` window carefully and activate the checkbox `I accept the conditions for MRI examinations`.
5	Select `OK`.

Note: The software will not permit further programming of an MRI mode without this confirmation.

6	Select **[Program]**.

WARNING
Risk of death due to deactivated ICD functions The MRI mode causes an ICD to be unable to detect dangerous heart rhythms and deliver any therapy shocks. An ICD patient must be continuously observed between activation of the MRI program and reactivation of the therapy program, and an external defibrillator must be kept constantly ready.

WARNING
Health risk to patients due to limited pacemaker or ICD function Continuous cardiological monitoring of the patient must be ensured until the device system's full functionality is restored in the follow-up examination.

7	Activate one of the possible MRI modes. The OFF setting is recommended for patients not dependent on their pacemaker. An asynchronous mode (D00, A00, V00) is recommended for pacemaker-dependent patients depending on the particular indication. If the patient shall receive biventricular pacing and an Evia HF(-T), Entovis HF(-T) pacemaker or an Ilesto HF-(T), Iforia HF-(T) ICD is implanted, an asynchronous biventricular pacing mode is recommended: depending on the indication D00-BiV or V00-BiV. • The following parameters are set for pacemakers: — Pulse amplitude: 4.8 V — Pulse width: 1.0 ms — Pacing rate: 80 bpm — All automatic functions and Home Monitoring are deactivated. — The magnet response is set to SYNC (synchronous). — For Evia HF-T/Entovis HF(-T): Home Monitoring remains active. • The following parameters are set for ICDs: — Pulse amplitude: 5.0 V — Pulse width: 1.0 ms — Pacing rate: adjustable from 70 to 160 bpm (preset to 90 bpm). — All automatic functions are deactivated. — ICD therapy is inactive. — The magnet response is set to SYNC (synchronous). — Home Monitoring remains active. — The programmed settings for the LV lead in normal mode are accepted for the biventricular MRI mode.

Note: You will leave the MRI program if you change parameters prior to sending (exception: the pacing rate for the ICD).

8	Transmit the MRI program to the pacemaker or ICD.

Note: When programming the MRI mode, the original pacemaker settings are saved in the programmer or the original ICD settings are saved in the ICD. These settings can be accessed again during the cardiological follow-up examination after completion of the MR scan, which simplifies restoration of the status from before the MR scan. For pacemakers, the same programmer must be used as for the preliminary examination.

9	Print and document follow-up data (print report).
10	Finish the preliminary examination of the patient. Make sure that the patient can be immediately submitted to cardiological follow-up after completion of the MR scan.

MRI Examination

Prerequisites

The following conditions have to be met:

- The contraindications listed in the respective sections as well as the required preconditions and basic conditions are taken into consideration.
- The patient was previously examined by a cardiology professional and the pacemaker or ICD is switched to a mode especially suitable for an MR scan.
- The technical and organizational conditions are met to be able to comply with the restrictions and safety measures required during the MR scan.
- Emergency equipment for resuscitation (including specialist staff certified to use it) are available.

Basic conditions and restrictions

The conditions that have to be met during an MR scan are listed in the section Preconditions and Basic Conditions for all Products, p. 12 under the subheading "Restrictions during the MR scan".

The conditions listed in the section Conditions for Specific Products, p. 14 also have to be observed.

Completion of the examination

After completing the MR scan, make sure the patient is again monitored by a cardiology professional, who performs the required follow-up cardiology examination and the reprogramming of the device system.

Follow-up

After the MR scan

Subsequent to the MR scan, the patient must immediately undergo cardiological follow-up.

This is necessary for the patient's safety for two reasons:

- To switch the active device back into a mode which provides the patient with adequate therapy.
- To check whether the device system or the heart muscle have incurred damage during the MR scan.

Cardiological follow-up procedure

The cardiological examination following an MR scan is to be performed as follows:

CAUTION
Risk of death for ICD patients Reactivation of the ICD therapy functions may be life-saving for an ICD patient. The patient can stop being continuously monitored and an external defibrillator no longer needs to be kept ready after these functions have been reliably reactivated.

1	Apply the programming head.
2	Interrogate the device.
3	Reactivate the program which was effective prior to programming the MRI mode.
4	If the active device is an ICD: reactivate ICD therapy.
5	Send the reactivated program to the device.
6	Perform a complete follow-up.
7	If necessary: perform further examinations.
8	Print and document follow-up data (print report).
9	Finish the follow-up for the patient.

4 Appendix A

MR Conditional Symbol on the Label

There is a sticker on the box with product information and symbols which are explained in the user manual provided in the packaging of the BIOTRONIK devices.

The packaging of MR conditional products under the brand name ProMRI is additionally labeled with the following symbol:

	MR conditional: Patients who have a device system with devices labeled with this symbol on the packaging can be examined using an MR scan under precisely defined conditions.

5 Appendix B

Combinations of Specific Products

These tables show which combinations of ICDs or pacemakers and leads can be used as a device system that is tested MR conditional.

	Safio S	Corox ProMRI OTW BP	Corox ProMRI OTW-S BP	Corox ProMRI OTW-L BP
Evia SR(-T) Evia DR(-T)	x			
Entovis SR(-T) Entovis DR(-T)	x			
Estella SR(-T) Estella DR(-T)	x			
Ecuro SR(-T) Ecuro DR(-T)	x			
Evia HF(-T)	x	x	x	x
Entovis HF(-T)	x	x	x	x

	Solia S	Solia T	Corox ProMRI OTW BP	Corox ProMRI OTW-S BP	Corox ProMRI OTW-L BP
Evia SR(-T) Evia DR(-T)	x	x			
Entovis SR(-T) Entovis DR(-T)	x	x			
Estella SR(-T) Estella DR(-T)	x	x			
Ecuro SR(-T) Ecuro DR(-T)	x	x			
Evia HF(-T)	x	x	x	x	x
Entovis HF(-T)	x	x	x	x	x

CAUTION

Limitation due to lead combinations that are not MR conditional

Combinations of ICDs or pacemakers and leads which are not listed are considered tested non-MR conditional.
The combination of Safio and Solia leads in a device system is not an MR conditional device system.

	Solia S	Linox^{smart} ProMRI S	Linox^{smart} ProMRI SD	Linox^{smart} ProMRI S DX	Corox ProMRI OTW BP	Corox ProMRI OTW-S BP	Corox ProMRI OTW-L BP
Iforia 5 VR-T Iforia 7 VR-T Ilesto 5 VR-T Ilesto 7 VR-T Lumax 740 VR-T Lumax 640 VR-T		x	x				
Iforia 5 VR-T DX Iforia 7 VR-T DX Ilesto 5 VR-T DX Ilesto 7 VR-T DX Lumax 740 VR-T DX Lumax 640 VR-T DX				x			
Iforia 5 DR-T Iforia 7 DR-T Ilesto 5 DR-T Ilesto 7 DR-T Lumax 740 DR-T Lumax 640 DR-T	x	x	x				
Iforia 5 HF-T Iforia 7 HF-T Ilesto 5 HF-T Ilesto 7 HF-T Lumax 740 HF-T Lumax 640 HF-T	x	x	x		x	x	x

	Solia S	Linox^{smart} ProMRI DF4 SD	Corox ProMRI OTW BP	Corox ProMRI OTW-S BP	Corox ProMRI OTW-L BP
Iforia 5 VR-T DF4 Iforia 7 VR-T DF4 Ilesto 5 VR-T DF4 Ilesto 7 VR-T DF4		x			
Iforia 5 DR-T DF4 Iforia 7 DR-T DF4 Ilesto 5 DR-T DF4 Ilesto 7 DR-T DF4	x	x			
Iforia 5 HF-T DF4 Iforia 7 HF-T DF4 Ilesto 5 HF-T DF4 Ilesto 7 HF-T DF4	x	x	x	x	x

CAUTION

Limitation due to lead combinations that are not MR conditional

Combinations of ICDs or pacemakers and leads which are not listed are considered tested non-MR conditional.

© BIOTRONIK SE & Co. KG
All rights reserved. Specifications
subject to modification, revision
and improvement.

® ProMRI is a registered trademark of
BIOTRONIK SE & Co. KG

CE 0123 (2012)
90/385/EEC

13-D-07
Revision: T (2013-01-23)

371712

BIOTRONIK SE & Co. KG
Woermannkehre 1
12359 Berlin · Germany
Tel +49 (0)30 68905-0
Fax +49 (0)30 6852804
sales@biotronik.com
www.biotronik.com

BIOTRONIK
excellence for life